Attorney Docket No.: Q85654

Application No.: 10/519,990

REMARKS

This Amendment is filed in response to the Final Office Action dated October 16, 2007, and is respectfully submitted to be fully responsive to the rejections raised therein. Accordingly, favorable reconsideration on the merits and allowance is respectfully submitted to be proper.

The amendments and how they respond to the rejections set forth in the Office Action are explained below in detail.

In the present Amendment, claim 1 has been amended to recite that the beta-thalassaemia is therapeutically treated by induction. Support for this amendment can be found on page 6, lines 23-24, for example.

Claims 3 and 4 have been amended to delete "further" and the amendments are directed to form only.

No new matter has been added. Entry of the Amendment is respectfully submitted to be proper. Upon entry of the Amendment, claims 1-4 will be all the claims pending in the application.

I. Response to Rejections Under 35 U.S.C. §§ 102(a) and 103(a)

Claim 1 stands rejected under 35 U.S.C. § 102(a) as assertedly being anticipated by Johnston et al. <u>Blood</u>, 98(11): 410, **2001** ("Johnston").

Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnston in view of Rachmilewitz, <u>British Journal of Haematology</u>, 91: 263-268, **1995** ("Rachmilewitz").

Applicants traverse and respectfully request reconsideration and withdrawal of the rejection in view of the amendment to claim 1 and in view of the following remarks.

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Johnston does not disclose, teach or suggest that rapamycin would be beneficial to thalassemic patients as a HbF inducer, and therefore does not anticipate or render obvious present claim 1. Claim 1, as amended, is directed to a method of treating beta-thalassaemia comprising administering a medicament comprising a pharmaceutically effective amount of rapamycin or a structural analogue thereof to a patient in need of such treatment, wherein the beta-thalassaemia is therapeutically treated by induction of HbF.

As mentioned in the previous amendment filed August 6, 2007, the approach described by Johnston is relative to gene therapy. Specifically, Johnston describes a development of a gene therapy system based on inducible AAV vectors. The vectors carry a "therapeutic gene" (in the described case the erythropoietin gene, but the technology can be applied to many other genes) under the control of a transcription activation system. There is no teaching by Johnston that rapamycin would be useful to thalassemic patients as a HbF inducer. Thus, Johnson does not disclose, teach or suggest all the limitations of claim 1 alone or in combination with Rachmilewitz.

II. Response to Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 3 and 4 stand rejected under 35 U.S.C. § 112, second paragraph as assertedly being indefinite.

Applicants submit that the amendment to claims 3 and 4 obviate the rejections and respectfully request reconsideration in view of the amendments. Accordingly, withdrawal of the rejection is respectfully requested.

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III. Conclusion

In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is

kindly requested to contact the undersigned attorney at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

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CUSTOMER NUMBER

Date: February 19, 2008

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